American Water Works Association

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Division of Toxicology and Human Health Sciences
Agency for Toxic Substances and Disease Registry
1600 Clifton Rd. NE
MS F–57
Atlanta, GA, 30329

RE: Draft Toxicological Profile: Perfluoroalkyls, Docket No. ATSDR–2015–0004

Dear Sir or Madam:

The American Water Works Association appreciates the opportunity to comment on the Agency for Toxic Substances and Disease Registry draft analysis of perfluoroalkyl substances, Toxicological Profile for Perfluoroalkyls. A number of household and community drinking water wells are contaminated with PFAS compounds including those evaluated by ATSDR, consequently, having a clearer understanding of the risk posed by PFAS compounds individually and as a class of compounds is important.

The Toxicological Profile is an important opportunity for the federal government to communicate what risk is posed by PFAS. In this regard, AWWA recommends ATSDR:

1. Present its findings in a clear and consistent fashion.
2. More closely coordinate with other federal agencies with relevant expertise, particularly the U.S. Environmental Protection Agency.
3. Adhere closely to well-established guidelines for use of the best available data and relevant data, as well as sound quality assurance and control procedures.
4. More clearly describe the research gaps and avenues to address research needs to develop sound risk assessments for PFAS compounds individually and as a group.

A timely and well-structured discussion of PFAS health effects is needed. There are estimates of more than 5,000 known PFAS compounds. EPA has reviewed more than 900 PFAS compounds for entry into commerce under the Toxic Substance Control Act since 2006.[1] An estimated 38 PFAS compounds are approved for use in food packaging.[2] At present, several states are developing ground water clean up standards and drinking water standards. This activity is occurring without a

[1] EPA, Presentation by Jeff Morris, accessed July 9, 2018 at https://www.epa.gov/sites/production/files/2018-05/documents/pfas_summit_jeff_morris_22_may_2018.pdf.

[2] EDF, Washington State takes action to eliminate use of PFAS in food packaging, accessed August 13, 2018 at http://blogs.edf.org/health/2018/03/08/washington-state-action-eliminate-pfas-food-packaging/ .

cohesive national policy discussion of the risk posed by low-level exposure to PFAS compounds individually or as a group. AWWA appreciates that the ATSDR has taken an important step in organizing the available data around 14 PFAS compounds. AWWA encourages ATSDR and EPA to work with stakeholders with relevant expertise and roles in PFAS risk management to fully characterize the risks, exposure pathways of concern, and appropriate risk mitigation strategies for PFAS compounds of potential public health concern.

ATSDR has a responsibility to focus on what it can reliably demonstrate. When ATSDR introduces an analysis like the Toxicological Profile into a topic with the high levels of public awareness and concern like that currently focused on PFAS, it must work to build scientific consensus around well-understood science. While PFAS compounds bioaccumulate, it is not clear how both of the following can be true:

1. ATSDR's summary fact sheet, Perfluoroalkyls – ToxFAQs™, reads, *"Research suggest that **high levels** of **certain** PFAs **may**: increase cholesterol levels, … lower infant birth weights; however, the decrease in birth weight is small and may not affect the infant's health."* [additional emphasis added]

2. The Toxicological Profile presents provisional minimum risk levels that, when applied using standard methodologies, lead to risk management measures at low nanogram per liter concentrations in drinking water.

It is very difficult for water systems to explain the risks and cost consequences of managing PFAS to customers using the Toxicological Profile as currently drafted. The Toxicological Profile documents both the historic pattern of PFAS production and historical high levels, and now declining levels of the few well-monitored PFAS compound concentrations in human body fluids. It describes a lengthy list of individual toxicological and epidemiological studies, providing information for the informed reader to consider, including strengths, limitations and inconsistencies in observations among the available studies. The Toxicological Profile then goes on to develop provisional MRLs that extrapolate to levels of health concern in humans at concentrations 300 times lower than observed adverse effects in animal models and advises that risk management should be based on a semi-acute endpoint.

Water systems, state regulators and the public will perceive the ASTDR's final MRLs as "bright line" thresholds rather than utilize the much more carefully caveated Toxicological Profile. Consequently, ASTDR should review the provisional MRLs to be sure that the final MRLs are consistent with the weight of evidence as described in the Toxicological Profile. Equally importantly, it should develop a communication strategy that provides a context for using the final Toxicological Profile and MRLs. This challenge is not limited to publications prepared by ASTDR; this problem also vexes work products from EPA, the National Toxicology Program, and individual state agencies.

Where ATSDR's analysis is policy-based, it should be transparent and take steps to ensure the policy premise is consistent with the existing risk management framework. To this end, ATSDR should be effectively coordinating with other federal agencies. For example, the draft Toxicological Profile incorporates a 10x "modifying" factor for immunotoxicity in calculating the perfluorooctane sulfonate provisional MRL. This factor is a policy decision rather than a summary of available science.[3]

[3] ASTDR, Toxicological Profile Perfluoroalkyls, page 80.

Assessments conducted by EPA, NTP, and Health Canada in 2016 point to an interest in immunotoxicity as a potential endpoint of concern but note that the available data is not adequate to support decision-making.[4,5,6] EPA manages the regulatory frameworks for controlling environmental exposure, so ATSDR should be certain its approach is consistent with EPA's risk management framework. EPA does not apply an arbitrary "modifying" factor to account for a toxicological endpoint of interest absent data sufficient to actually set a level of health concern under the Safe Drinking Water Act.

ATSDR must adhere to recognized standards of care when compiling influential documents like the Toxicologic Profile: Perfluoroalkyls. The Toxicological Profile should meet Office of Management and Budget Guidelines and adhere to well-established principles for risk assessment.[7, 8,9,10] While the Toxicological Profile was subjected to external peer-review, it is unreasonable to expect that four external reviewers would be able to fully vet an 852-page document. Considering the large number of studies reviewed in the ATSDR analysis it is not clear why the Agency made some of the selections it did. For example, the provisional MRL for intermediate oral exposure to perfluorooctanoic acid is based on two studies, both of which had only a single test dose (i.e., Koskela et al. 2016; Onishchenko et al. 2011). In addition, these two animal studies report markedly different adverse health endpoints.

The ATSDR's approach to setting the provisional MRL is based on selecting a point of departure using animal serum perfluoroalkyl levels for sensitive endpoints, which are then extrapolated to humans for an exposure of intermediate duration (e.g., a period of days or weeks). This analytical approach carries the implied assumption that a few days of exposure to PFAS compounds at the MRL may lead to adverse health consequences. The current methodology may be consistent with an analysis of lifetime, chronic exposure where bioaccumulation can lead to a substantial dose but may not be appropriate without supporting physiologically based pharmacokinetic modeling for a shorter-term risk assessment. ATSDR looked for and did not find any suitably robust PBPK models for this task.[11] Given the limited understanding of relevant physiology it is not clear why ASTDR did not use another analytical strategy that would more convincingly align with the use scenario for the provisional MRL. EPA's health advisories for PFOA and PFOS reflect a lifetime level, which the Agency then describes as a shorter-term concern for risk management with respect to sensitive sub-populations.[12,13]

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[4] EPA, Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS), 2016.
[5] NTP, Monograph on immunotoxicity associated with exposure to perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program. 2017.
[6] Federal-Provincial-Territorial Committee on Drinking Water, Perfluorooctane Sulfonate (PFOS) in Drinking Water Document for Public Consultation. 2016.
[7] OMB, Circular A-4, accessed August 13, 2018 at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.
[8] HHS, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, 2002
[9] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, 2002
[10] EPA, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, 2003.
[11] ASTDR, Toxicological Profile Perfluoroalkyls, page 5.
[12] EPA, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA), 2016.
[13] EPA, Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS), 2016.

Research gaps are preventing cost-effective risk assessment and mitigation. AWWA appreciates ASTDR attempting to evaluate the risk posed by PFAS compounds beyond PFOA and PFOS. While this family of compounds have been in commerce since the 1950's and almost 1,000 unique PFAS compounds have been introduced into commerce under TSCA in the last decade alone, the health effects literature is not sufficient to easily arrive at a consensus view of the health risk posed by PFOS or PFOA. At best, there is a small set of additional PFAS compounds for which there is a useful body of toxicological research. AWWA encourages ATSDR and EPA to work with stakeholders with relevant expertise and roles in PFAS risk management to develop a cohesive research program so that risk management measures (e.g., product reformulation, contaminated site remediation, waste stream controls, and drinking water treatment) can be effectively targeted and applied.

Thank you for the opportunity to comment on ATSDR draft Toxicological Profile. If you have any questions regarding this correspondence or if AWWA can be of assistance in some other way, please contact me or Steve Via at (202) 326-6130 or svia@awwa.org.

Best regards,

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Who is AWWA

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.